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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20857

CITIZEN PETITION

The undersigned, Teva Pharmaceuticals USA, Inc. ("Teva USA"), submits this petition under 21 U.S.C. § 355(j)(5)(B) and 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to determine that the approved application of Mylan Pharmaceuticals, Inc. ("Mylan") for nifedipine extended-release tablets ("nifedipine XL"), 30 mg (ANDA 75-108) is no longer eligible for 180-day exclusivity, or, that even if it were so eligible, any such exclusivity will expire on August 29, 2000 or, at the latest, 180 days after the first commercial marketing of Mylan's authorized "generic" nifedipine XL 30 mg product pursuant to its license from Pfizer Inc.

A. Action Requested

On March 2, 2000, Mylan Pharmaceuticals, Inc. ("Mylan") announced a deal with Pfizer settling patent infringement litigation over the 30 mg strength of Pfizer's Procardia® XL (nifedipine extended-release tablets, 30 mg). Under this deal, Pfizer's patent infringement suit against Mylan was dismissed, and Pfizer licensed to Mylan the right to market 30 mg, 60 mg, and 90 mg strengths of Procardia XL as so-called "generic" products.

Under current FDA policy, the net effect of this deal will be to exploit Mylan's claim to 180-day exclusivity on 30 mg nifedipine XL so as to block all true generic versions of this drug product from the market until the expiration of the last applicable patent in 2010 or until there is a qualifying court decision in another applicant's patent litigation over nifedipine XL, which could be years away. Such an outcome would be profoundly harmful to consumers and contrary to the letter and intent of the law.

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Accordingly, the petitioner calls upon FDA to uphold the law and the public interest by determining that Mylan's ANDA for nifedipine XL 30 mg no longer qualifies for 180-day exclusivity under the statute, such that other ANDAs for nifedipine XL 30 mg may be given effective approval immediately. In the event FDA is unwilling to make such a determination, petitioner requests FDA to determine that any 180-day exclusivity period to which Mylan may have been entitled began on the date the Mylan-Pfizer deal was concluded (March 2, 2000) or, at the latest, on the date Mylan began to market its authorized "generic" nifedipine XL 30 mg product under that deal. Such a determination would enable other ANDAs for nifedipine XL 30 mg to be given effective approval as of August 29, 2000 or, at the latest, 180 days after the first marketing of Mylan's authorized "generic" product.

B. Statement of Grounds

I. Factual Background

As the first sponsor to file an abbreviated new drug application ("ANDA") for the 30 mg strength of Procardia XL containing a challenge to Pfizer's patents covering that drug product ("Paragraph IV ANDA"), Mylan became eligible for 180 days of exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv) as to that product. Accordingly, under the statute, any subsequent paragraph IV ANDA for that product would be ineligible for final approval until 180 days after the occurrence of one of two events: a qualifying court decision holding a challenged patent invalid, unenforceable, or not infringed, or Mylan's first commercial marketing of its nifedipine XL 30 mg product.

Mylan's deal with Pfizer allowing Mylan to market Pfizer's product, however, means that Mylan now has access to an "authorized generic" version of Procardia XL 30 mg, as well as the 60 and 90 mg strengths. Accordingly, Mylan has no need to market its own 30 mg nifedipine XL product. Indeed, Mylan has every reason not to market its own 30 mg product, because, as FDA is currently interpreting the law, so long as Mylan refrains from marketing that product, the 180-day exclusivity clock on that product will not begin (unless there is a qualifying court decision in another applicant's patent case), and therefore no other applicant will be able to bring a 30 mg generic nifedipine XL product to market – leaving Pfizer and Mylan in unchallenged joint control of the market for that product. This arrangement, moreover, will actually enable Mylan to monopolize the entire generic market for nifedipine XL, because even though Mylan's competitors may be able to market the 60 or the 90 mg strength, they will not be able to offer the full line of nifedipine XL strengths, and therefore will be at a decisive disadvantage in the marketplace.

This cynical attempt to manipulate the statute in order to block true generic versions of nifedipine XL 30 mg from the market is so obviously contrary to the underlying intent of the law that it must be immediately and decisively overturned. Fortunately, FDA has ample authority to do so – and indeed is legally compelled to do so – under several provisions of law and regulation.

II. Mylan's ANDA For Nifedipine XL 30 mg Is No Longer A Paragraph IV ANDA

By definition, a paragraph IV certification is one which alleges that a patent covering the reference listed drug is invalid, will not be infringed by the generic product that is the subject of the ANDA, or is unenforceable. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(*4*). In short, a paragraph IV ANDA, by definition, must challenge a blocking patent. In the absence of such a challenge, the ANDA is not a paragraph IV ANDA.

In this case, Mylan's paragraph IV patent challenge on nifedipine XL 30 mg resulted in a patent infringement lawsuit against Mylan by the patent holder and NDA holder (Bayer AG and Pfizer). Had Mylan won that lawsuit, it would have been legally free and clear to market its own generic nifedipine XL 30 mg product – representing, in effect, a victorious culmination of the patent challenge. Had Mylan lost, it would have been forced to await patent expiration before receiving effective approval of its ANDA. Accordingly, Mylan would have been required to amend its patent certification to a paragraph III certification, signifying that it was no longer challenging the patent. Alternatively, had Mylan never been sued at all within the applicable 45-day window, its ANDA would have been eligible for effective approval immediately upon completion of substantive review without regard to the patent, allowing Mylan to market the product while still, in effect, maintaining its challenge to the patent.

Mylan's settlement with Pfizer, however, avoided any of these outcomes. Instead, that settlement resulted in an agreed dismissal of the lawsuit without judicial resolution of the patent challenge. And through this agreed dismissal, Mylan has dropped its challenge to the patent that was the subject of the case. As a result, the basis for Mylan's paragraph IV certification – its challenge to the patent – has disappeared. Mylan's ANDA for nifedipine XL 30 mg is therefore no longer entitled to be treated as a paragraph IV ANDA.[1]

As a necessary consequence of that change in status, Mylan is no longer eligible for 180-day exclusivity for its nifedipine XL 30 mg ANDA. Only an ANDA "containing" a paragraph IV ANDA is eligible for the 180-day exclusivity, 21 U.S.C. § 355(j)(5)(B)(iv). It follows that once an ANDA ceases to contain a paragraph IV certification, it is no longer eligible for that exclusivity.

This conclusion is not only consistent with the language of the statute, but also with the policy underlying the statute. As FDA itself has acknowledged, 180-day exclusivity "can be interpreted as a reward not only for the benefit provided to subsequent ANDA applicants but for the benefit to the public of removing an obstacle to competition . . . . Therefore, the 180-day

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[1] FDA discussed this issue in the preamble to its August 1999 proposed rule on 180-day exclusivity; in that discussion, the agency neither rejected nor accepted the view that a settlement renders a paragraph IV applicant ineligible for exclusivity, but merely stated that it believed its proposed "triggering approach" was preferable. 180-Day Exclusivity for Generic Drug Applications, 64 Fed. Reg. 42,873, 42,880 (1999).

period is available to the applicant who resolves an issue of patent coverage . . . ."[2] In this case, Mylan has provided no benefit either to subsequent generic applicants nor to the public, has done nothing to "remove an obstacle to competition" – in fact, quite the contrary – and has not resolved any issue of patent coverage. It should therefore not benefit from the reward of 180-day exclusivity.

Likewise, it is universally accepted that the 180-day exclusivity clause was never intended to create opportunities for drug companies to indefinitely obstruct the market entry of generic drugs by entering into commercial arrangements which, like the Mylan-Pfizer deal, prevent the 180-day period from ever being triggered. As FDA stated in the preamble to last year's proposed rule on the 180-day exclusivity:

> Licensing agreements and other arrangements between an innovator company and the generic drug company who is the first ANDA applicant to file a paragraph IV certification can be of considerable financial benefit to the companies involved, but also may contribute to delayed generic competition by forestalling the beginning, or triggering, of the 180-day exclusivity period. These arrangements can create almost insurmountable barriers to the final approval and marketing of generic dug products that are otherwise ready for final approval. These barriers thwart a major congressional goal underlying the passage of the Hatch-Waxman amendments.[3]

The petitioner respectfully submits that in the case at hand, the means of surmounting the barrier that Mylan and Pfizer have tried to create by their settlement deal are readily at hand in the law itself, and in fact are mandated by that law. Under the circumstances presented by this deal, Mylan's ANDA is in reality no longer one that "contains" a certification challenging the patent – regardless of which piece of paper physically resides in the ANDA file – because by definition, a generic applicant that has settled with the patent holder in a manner that results in no generic product reaching the market is no longer challenging the patent.[4] Accordingly, the

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[2] Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,895 (1989) (preamble to proposed rule).

[3] Id. at 42,874-42,875 (emphasis added). Similarly, as the court held in Mylan Pharmaceuticals, Inc. v. Henney, 94 F. Supp. 2d 36, 53 (D.D.C. 2000), commenting on a deal very similar to the Mylan-Pfizer deal at issue here:

> Courts are advised that statutes should not be interpreted so as to create anticompetitive effects [cites omitted]. . . . Hatch-Waxman [is] intended to provide an *incentive* for drug companies to explore new drugs, not a market "windfall" for crafty, albeit industrious, market players.

[4] Mylan and Pfizer have publicly asserted that their settlement deal does not prevent Mylan from marketing its own 30 mg nifedipine XL product, but that any decision not to do so is Mylan's alone. However, whether or not this is true in a narrow technical sense – and it is impossible to know given that Mylan and Pfizer have concealed the terms of their deal – it is highly unlikely that Pfizer would have agreed to the deal if it expected Mylan to market its own 30 mg generic product, thus opening the entire nifedipine market to generic competition (precisely the situation the deal appears intended to avoid). Indeed, under the circumstances of this deal, it would make no sense whatsoever for Mylan to market its own nifedipine 30 XL and face the possibility of damages for patent infringement that could far exceed any net income Mylan might receive from such marketing, when it can safely sell Procardia XL

petitioner calls upon FDA to recognize that Mylan has relinquished its paragraph IV patent challenge by its deal with Pfizer and has therefore rendered its nifedipine XL 30 mg ANDA ineligible for the 180-day exclusivity. This decision could be given effect either by requiring Mylan to amend its certification to a paragraph III, or simply by ceasing to treat Mylan's ANDA as a paragraph IV ANDA eligible for the 180-day exclusivity, opening the way for immediate effective approval of competing generic products.[5]

III. The Mylan-Pfizer Deal Constitutes Commercial Marketing And Has Therefore Triggered the 180-Day Exclusivity

Whatever its outward form, the essence of the Mylan-Pfizer deal is that Mylan has committed itself not to market its own 30 mg generic nifedipine XL product in exchange for valuable consideration, namely Pfizer's dropping of its patent infringement lawsuit against Mylan and licensing to Mylan of marketing rights to Procardia XL as an authorized "generic." Of course, Mylan and Pfizer, having observed the antitrust difficulties other companies have found themselves in over explicit agreements to withhold generic products from the market, have been careful to avoid any such explicit agreements. But, as noted above, it takes very little insight to understand that the deal's net effect – and underlying design – is that Mylan will in fact keep its own generic product off the market, whether or not it is explicitly bound to do so.

Thus, Mylan has in a very real sense bargained away the rights to its own generic product under its 30 mg nifedipine XL ANDA in exchange for commercial consideration. Because this is the essence of commercial marketing, FDA should recognize that the commercial marketing trigger of the 180-day provision, 21 U.S.C. 355(j)(5)(B)(iv)(I), was activated on the day the deal was struck, March 2, 2000, and will accordingly expire on August 29, 2000. Alternatively, FDA should recognize that "commercial marketing" took place on the date the Mylan authorized "generic" was introduced to the market pursuant to the Mylan-Pfizer deal, such that Mylan's claim to exclusivity will expire 180 days after that date.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact

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as an "authorized" generic. Thus, whatever the facial terms of the deal, its practical effect is to preclude Mylan from marketing its own product under its ANDA.

[5] Cf. 21 C.F.R. § 314.94(a)(12)(viii)(C) ("an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate") (emphasis added). Although this regulation is cast in terms of the period prior to approval of the application, there is no reason why its underlying logic should not apply equally to the period after approval. In any event, an applicant who learns that any material element of a pending or approved application is no longer accurate has a moral and legal duty to correct its application accordingly. Cf. 21 U.S.C. § 355(e); 21 U.S.C. § 314.150(a)(2)(iv) (requirement that FDA move to withdraw the approval of any application or abbreviated application found to contain any untrue statement of material fact).

This information will be provided upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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